THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

KATHERINE CROCKETT, **Plaintiff,** **v.** **LUITPOLD PHARMACEUTICALS, INC., AMERICAN REGENT, INC., DAIICHI SANKYO, INC., DAIICHI SANKYO CO., LTD., VIFOR PHARMACEUTICALS MANAGEMENT, LTD AND VIFOR PHARMA-ASPEREVA PHARMACEUTICALS, INC.,** **Defendants.**	**CIVIL ACTION** **NO. 19-276**

OPINION

Plaintiff Katherine Crockett brings negligence, fraud, strict liability, breach of warranty, and breach of consumer protection law claims following purported adverse effects she suffered after receiving injections of Injectafer, a medication prescribed to treat iron deficiency anemia. Defendants American Regent, Inc., formerly known as Luitpold Pharmaceuticals, Inc.,[1] Daiichi Sankyo, Inc., and Daiichi Sankyo US Holdings, Inc. (collectively, "Defendants") move to dismiss most of the Complaint pursuant to Federal Rules of Civil Procedure 8(a), 9(b), and 12(b)(6).

I. FACTS[2]

Injectafer is an iron replacement injection medication brought to market in the United States by Defendants for the treatment of iron deficiency anemia ("IDA") in adult patients who have intolerance to oral iron. The injection is to be administered intravenously in two doses

[1] Effective January 1, 2019, Luitpold Pharmaceuticals, Inc. merged with American Regent, Inc..

[2] These facts are drawn from the Complaint and, for the purposes of the motion to dismiss, will be taken as true. *See Kost v. Kozakiewicz*, 1 F.3d 176, 183 (3d Cir. 1993).

separated by at least seven days.

Injectafer is one of several products available for intravenous iron but is the only such product available in the United States formulated with the unique ferric carboxymaltose ("FCM") compound. FCM can cause a condition called severe hypophosphatemia ("Severe HPP"). Hypophosphatemia is an abnormally low level of phosphate in a person's blood, and the condition can be mild, moderate, severe, or persistent. Severe HPP has dangerous effects including muscle weakening, fatigue, severe nausea, and possible medical complications including cardiac arrest, respiratory failure, arrhythmias, and rhabdomyolysis (muscle breakdown).

Prior to its approval in the United States, FCM was available on the European and other markets under the brand name Ferinject—designed, manufactured, promoted, and sold by Defendant Vifor Pharmaceuticals. (Vifor licensed and continues to license FCM to all other Defendants.) During FCM's presence on the European and United States markets, dozens of case reports and pieces of medical literature emerged that revealed the link between FCM and Severe HPP. The studies, of which Defendants were on notice, revealed an increasing number of case reports of intravenous-iron patients developing Severe HPP. In one study, all 18 cases of severe and life-threatening HPP developed after administration of FCM. In another study, of the 78 patients taking FCM, 51% developed HPP, including 13% with Severe HPP. Defendants also had knowledge of the link between Injectafer and Severe HPP from their own clinical studies.

When Luitpold Pharmaceuticals, Inc. ("Luitpold") first submitted a New Drug Application for Injectafer to the Food and Drug Administration ("FDA") in 2006, it received a non-approvable letter in response due to the FDA's clinical safety concerns. Luitpold applied again in September 2007 and received another non-approvable letter, which cited "clinically

important hypophosphatemia" as a concern. Injectafer eventually received FDA approval, and in 2013 Defendants brought Injectafer to the United States market.

Since then, Injectafer's label has at all times omitted any reference to "Severe HPP" or "clinically important hypophosphatemia."[3] HPP is not listed in the warning sections or in any kind of "black box" warning, but instead is listed as an "adverse reaction" occurring in less than two percent of patients. From July 2013 until January 2018, the Patient Information leaflet referred to "asymptomatic reductions in blood phosphorus." In January 2018, Defendants removed the term "asymptomatic" and simply listed "low levels of phosphorous in your blood" in the leaflet. The "Adverse Reactions in Clinical Trials" section of the labeling refers to "transient decreases in laboratory blood phosphorous levels (< 2 mg/dl)." The labeling makes no reference to clinical conditions associated with Severe HPP, including cardiac arrest, respiratory failure, arrhythmias, and rhabdomyolysis (muscle breakdown). The labeling also does not reference FCM's known effect on the FGF23 hormone, which is associated with a decrease in blood phosphorous and can induce HPP.

Plaintiff, a Pennsylvania resident, was prescribed Injectafer for the treatment of her IDA at the Mayo Clinic in Rochester, Minnesota. Plaintiff received her first Injectafer injection at the Mayo Clinic on May 5, 2017, and her second injection in Philadelphia, Pennsylvania on May 16, 2017. After her first injection, Plaintiff's blood phosphate levels dropped to 1.6 mg/dl, as measured on May 11, and further dropped to 1.2 mg/dl after her second injection, as measured

[3] Defendants have attached to their motion to dismiss a copy of the Injectafer Prescribing Information from July 2013, which they allege was in effect at the time of Plaintiff's prescription. "[A] court may consider any undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document" without converting a motion to dismiss into one for summary judgment. *Pension Benefit Guar. Corp. v. White Consol. Indus.*, 998 F.2d 1192, 1196 (3d Cir. 1993). Neither party disputes the authenticity of the Prescribing Information. Given that Plaintiff's Complaint challenges Injectafer's labeling, warning, and patient information, the Prescribing Information may be considered in ruling on Defendants' motion to dismiss.

on May 19. She was subsequently diagnosed with Severe HPP. Plaintiff suffered from severe nausea, pain, weakness, and constant fatigue, and was additionally diagnosed with "renal phosphate wasting." Plaintiff had to take a leave of absence from work and was only able to return on limited duties after several months. Plaintiff filed this suit, alleging that she suffered and likely will continue to suffer severe and permanent injuries and damages as a result of taking Injectafer. Defendants have now moved to dismiss all claims, in whole or in part.

II. LEGAL STANDARDS

When evaluating a complaint, factual allegations are scrutinized under Rules 8(a) and 12(b)(6) to determine if the allegations and inferences proposed from those allegations are plausible. *See Ashcroft v. Iqbal*, 556 U.S. 662, 683 (2009). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *See id.* at 678 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

"In light of *Twombly*, 'it is no longer sufficient to allege mere elements of a cause of action; instead a complaint must allege facts suggestive of [the proscribed] conduct.'" *Great W. Mining & Mineral Co. v. Fox Rothschild LLP*, 615 F.3d 159, 177 (3d Cir. 2010) (quoting *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)). "[R]ote recitals of the elements of a cause of action, legal conclusions, and mere conclusory statements" are disregarded. *James v. City of Wilkes-Barre*, 700 F.3d 675, 679 (3d Cir. 2012). The relevant question is not whether the claimant "will ultimately prevail . . . but whether [the] complaint [is] sufficient to cross the federal court's threshold." *Skinner v. Switzer*, 562 U.S. 521, 531 (2011).

For claims that sound in fraud, Rule 9(b) requires the plaintiff to "state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions

of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). To satisfy this heightened pleading requirement, a complaint must provide "all of the essential factual background that would accompany the first paragraph of any newspaper story—that is the who, what, when, where, and how of the events at issue." *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002) (internal citations omitted).

III. ANALYSIS[4]

Plaintiff's Complaint includes 11 numbered claims. Each claim contains some or all of the following theories: that Defendants designed, developed, manufactured, marketed, promoted, monitored, labeled, sold, and distributed Injectafer while knowing or reasonably suspecting that the drug was dangerous. Count II is a negligent failure-to-warn claim. Count III is a negligent design defect claim. Count IV is a negligent misrepresentation claim. Count I is a catch-all negligence claim, which uses all the aforementioned theories to allege Defendants had a duty of care to patients and physicians which they breached in developing and distributing a drug they knew to be unreasonably dangerous without adequate warnings.[5] Count V is a fraud claim, alleging Defendants falsely represented Injectafer to patients and doctors by concealing its known risks to induce more Injectafer prescriptions. Counts VI and VII are strict liability claims for failure to warn and for design defect, respectively. Count VIII is a breach of express warranty claim, alleging Defendants represented through language in their labeling, advertising, and marketing materials that Injectafer was safe for patient use. Count IX is a breach of implied warranty claim, alleging that Defendants implied through their labeling, advertising, and

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[4] Federal courts sitting in diversity must apply the substantive law of the forum state. *See Erie R.R. Co. v. Tompkins*, 304 U.S. 64 (1938). Neither party disputes that Pennsylvania law governs this case.

[5] As pled, Count I (negligence) appears to contain a compilation of the allegations in Counts II through IV. The Pennsylvania Supreme Court has made clear that in negligence, "the substantive allegations are more important than the labels." *Lance*, 85 A.3d at 458. Still, pleadings should not be duplicative, and the Court finds no path to construe Count I here in a non-duplicative manner. Count I shall, accordingly, be dismissed without prejudice.

marketing that Injectafer was safe. Count X is a breach of state consumer protection laws claim, alleging Defendants deceived patients by claiming Injectafer was safe and advertising the drug in a way that created misunderstandings about its risks. Count XI is a gross negligence claim.[6] Additionally, Plaintiff seeks punitive damages.

Defendants' motion to dismiss focuses predominantly on the failure-to-warn and defective design theories. They make three threshold arguments: (1) *Hahn v. Richter*, 673 A.2d 888 (Pa. 1996), bars all non-negligence claims; (2) the negligence-based claims are preempted, in whole or in part, by federal law; and (3) the learned intermediary doctrine bars the common law fraud and Unfair Trade Practices and Consumer Protection Law ("UTPCPL") claims. The Court addresses these in turn, and then proceeds to address Defendants' arguments that all the claims are inadequately pled, either under Rule 8 or, as applicable, the heightened pleading standard of Rule 9(b).

A. The Applicability of *Hahn v. Richter*

Defendants first argue that *Hahn v. Richter*, 673 A.2d 888 (Pa. 1996), forecloses all of Plaintiff's non-negligence claims—namely, strict liability, breach of warranty, and fraud. Plaintiff says not so.

Hahn was a negligence and strict liability action brought under a failure-to-warn theory. In its decision, the Pennsylvania Supreme Court adopted Comment k to Section 402A of the Restatement (Second) of Torts,[7] and thereby "denied application of strict liability to products

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[6] "[T]here is no separate cause of action under Pennsylvania law for gross negligence." *Spence v. ESAB Grp., Inc.*, 623 F.3d 212, 215 n.2 (3d Cir. 2010); *see also Daly v. New Century Trans., Inc.*, 2012 WL 4060687, at *4 (M.D. Pa. Sept. 14, 2012) ("Pennsylvania law acknowledges differing standards of care, *but does not recognize degrees of negligence* as separate causes of action.") (emphasis added). Plaintiff's claim for gross negligence shall therefore be dismissed with prejudice.

[7] Comment k, titled "Unavoidably unsafe products," states: "There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not

such as prescription drugs, which, although dangerous in that they are not without medical risks, are not deemed defective and unreasonably dangerous when marketed with proper warnings." *Id.* at 889-90. The question before the Pennsylvania Supreme Court in *Hahn* was whether the trial court had erred in its instructions to the jury regarding applicable theories of liability in a negligence and strict liability action against drug manufacturers for failing to adequately warn physicians of a particular use of the drug at issue. *Id.* at 889. The trial court had given an instruction that liability could be found if the plaintiff's injuries were caused by the defendant's negligent failure to provide adequate warnings. *Id.* But it had declined to give a strict liability instruction, reasoning that in failure-to-warn prescription drug cases negligence was the only basis for recovery. *Id.* The Pennsylvania Supreme Court agreed, holding that the defendant "could be found liable if [the plaintiff's] injuries were caused by a negligent failure to provide adequate warnings. The court did not err in declining to give an instruction on strict liability." *Id.* at 891.

However, the court prefaced its holding with the remark that "where the adequacy of warnings associated with prescription drugs is at issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, i.e., the manufacturer's negligence, is the only recognized basis of liability." *Id.* Defendants seize on this statement to argue that *Hahn*—rather than

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uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk." Restatement (Second) of Torts § 402A cmt. k (1965) (emphasis in original).

simply addressing the issue at hand (whether strict liability claims are cognizable in a prescription drug failure-to-warn case)—addressed the much larger question of whether any claims other than negligence claims are cognizable in such cases. Specifically, Defendants seek to extend *Hahn*'s holding to bar—in addition to Plaintiff's strict liability claims—her breach of express and implied warranty as well as her fraud claims.

This extension of *Hahn*'s holding is not warranted in that the Pennsylvania Supreme Court's statement that "negligence . . . is the only recognized basis of liability," *id.*, is dicta by the court's own accounting. The court recognizes that "dicta is generally regarded as information in an opinion which is 'not necessary to the determination of the case.'" *BouSamra v. Excela Health*, 210 A.3d 967, 976 n.5 (Pa. 2019). Accordingly, it should be handled with caution in that it "often present risks of unforeseen complications and unintended consequences" which makes reliance on dicta "difficult to justify, if not ill advised." *Commonwealth v. Romero*, 183 A.3d 364, 400 n.18 (Pa. 2018). "[I]t is axiomatic that the holding of a judicial decision is to be read against its facts[,]" which "protects against an unintentional extension of governing principles beyond scenarios to which they rationally relate." *See Lance*, 85 A.3d at 453. Thus, "[d]ictum settles nothing, even in the court that utters it." *Romero*, 183 A.3d at 400 n.18 (citing *Jama v. Immigration & Customs Enf't*, 543 U.S. 335, 351 n.12 (2005)). And, simply because it is repeated in subsequent decisions, it is not thereby transformed into a holding. *See id.* Indeed, the Pennsylvania Supreme Court, while reaffirming that "[f]or policy reasons this Court has declined to extend strict liability into the prescription drug arena,"[8] *Lance*, 85 A.3d at 453, took

[8] In the absence of additional guidance from the Pennsylvania Supreme Court, trial courts in this Circuit have split on how broadly to read *Hahn*. In *Salvio v. Amgen, Inc.*, 810 F. Supp.2d 745, 755 (W.D. Pa. 2011), the court held that "a pharmaceutical manufacturer cannot be held liable for a claim that is not based in negligence[,]" but did so, as Defendants themselves note, in a case where the only non-negligence claim was breach of warranty. Defendants cite a handful of cases that interpreted *Hahn* broadly to bar all non-negligence claims. *See Kline v. Pfizer, Inc.*, 2008 WL 4787577, at *2-*3 (E.D. Pa. Oct. 31, 2008); *Colacicco v. Apotex, Inc.*, 432 F. Supp.2d 514, 548 (E.D. Pa. 2006), *rev'd on other grounds*, 521 F.3d 253 (3d Cir. 2008), *vacated*, 556 U.S. 1101 (2009); *Leonard v. Taro Pharm. USA,*

pains to clarify that, in doing so, "it simply has not immunized drug companies from other governing aspects of Pennsylvania tort law delineating product-manufacturer duties and liabilities." *Id.* Accordingly, any extension of *Hahn* beyond a conclusion that claims for strict liability are not cognizable in a prescription drug failure-to-warn case, should be carefully considered.[9]

Because *Hahn* barred strict liability claims against pharmaceutical manufacturers, it follows that Plaintiff's strict liability claims—Counts VI (failure-to-warn) and VII (design defect)—must be dismissed with prejudice.[10] As set forth below, the rationale underpinning *Hahn* applies to Plaintiff's breach of implied warranty claims as well so they, too, shall be dismissed with prejudice.

By statute, Pennsylvania implies a warranty of merchantability in a contract for the sale of goods if the seller is "a merchant with respect to the goods of that kind." 13 Pa. C.S.A. § 2314(a). Such warranty requires that the goods in question be "fit for the ordinary purposes for

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Inc., 2010 WL 4961647, at *5 (W.D. Pa. Dec. 2, 2010). Other courts have construed *Hahn* more narrowly, recognizing that *Hahn* did not speak to fraud or warranty claims. *See Bell v. Boehringer Ingelheim Pharms., Inc*, 2018 WL 928237, at *4 (W.D. Pa. Feb. 15, 2108) ("The court is persuaded that Pennsylvania law recognizes a cause of action for fraudulent marketing of prescription drugs."); *see also Tatum v. Takeda Pharms. N. America, Inc.*, 2012 WL 5182895, at *4 (E.D. Pa. Oct. 19, 2012) ("*Hahn* does not preclude [fraud] claims where the plaintiff alleges that the seller had actual knowledge of the risks of prescription drugs and intentionally concealed them."); *Doughtery v. C.R. Bard, Inc.*, 2012 WL 2940727, at *8-*9 (E.D. Pa. July 18, 2012) ("see[ing] no basis for declining to enforce a contractual promise expressly and voluntarily made by a manufacturer of prescription drugs" and "conclud[ing] that Pennsylvania law does not preclude express-warranty claims against manufacturers of prescription drugs").

[9] In denying application of strict liability to prescription drugs, *Hahn* relied, in addition to Comment k, on two Pennsylvania Supreme Court precedents and a Third Circuit opinion, but none of them addressed any arguments outside of negligence and strict liability. *See Incollingo*, 282 A.2d at 219-20 (plaintiff alleged only negligence claims, but the court also discussed strict liability); *Baldino v. Castagna*, 478 A.2d 807 (Pa. 1984) (negligence in drug marketing); *Mazur v. Merck & Co, Inc.*, 964 F.2d 1348, 1352 (3d Cir. 1992) (a negligence and strict liability failure-to-warn case).

[10] Although leave to amend should be freely granted "when justice so requires . . . a court may deny leave to amend when such amendment would be futile." *Budhun v. Reading Hosp. and Med. Ctr.*, 765 F.3d 245, 259 (3d Cir. 2014) (internal quotations omitted).

which such goods are used." 13 Pa. C.S.A. § 2314(b)(3). "As many courts have recognized, the theories of strict liability and breach of the implied warranty of merchantability are parallel theories of recovery, one in contract and the other in tort." *Doughtery*, 2012 WL 2940727 at *7 (internal quotations omitted) (collecting cases). Going back half a century, scholars have analyzed strict liability and breach of implied warranty as substantively the same—allowing recovery without the necessity of proving the defendant's negligence or fault. *See, e.g.*, William L. Prosser, *The Fall of the Citadel (Strict Liability to the Consumer)*, 50 Minn. L. Rev. 791, at 801-05 (1966).

In *Makripodis v. Merrell-Dow Pharmaceuticals, Inc.*, 523 A.2d 374 (Pa. Super. 1987), a Pennsylvania appellate court affirmed the dismissal of an implied warranty claim against a pharmacist in a prescription drug case. As the Superior Court explained, "[T]he very nature of prescription drugs themselves precludes the imposition of a warranty of fitness for 'ordinary purposes', as each individual for whom they are prescribed is a unique organism who must be examined by a physician who is aware of the nature of the patient's condition as well as the medical history of the patient." *Id.* at 377. In so holding, the court relied on Comment k—the same analytical foundation used in *Hahn*.[11] It would be inconsistent to exempt a drug manufacturer from strict liability for defective design or failure to warn under Comment k, but allow recovery for the same issue under a breach of implied warranty claim.[12] *See Doughtery*, 2012 WL 2940727 at *7 (coming to the same conclusion in the medical device context). Accordingly, Plaintiff's implied warranty claims are non-cognizable. Thus Count IX (breach of

[11] Plaintiff argues that *Makripodis* is about insulating a pharmacist from implied warranty liability, not a drug manufacturer, but this ignores the case's rationale as rooted in Comment k.

[12] Moreover, Plaintiff fails to cite any cases that have permitted an implied breach of warranty claim to proceed against a prescription drug manufacturer.

implied warranty) shall be dismissed with prejudice.

However, Plaintiff's claims for breach of express warranty and for fraud are not reached by *Hahn*'s rationale. While Defendants seek to dismiss them, they make no argument, choosing instead to cite to a series of non-precedential opinions. With respect to Plaintiff's claim for express warranty, Defendants cite to *Salvio*, 810 F. Supp.2d 745, and *Rowland v. Novartis Pharmaceuticals Corp.*, 34 F. Supp.3d 556 (W.D. Pa. 2014). But, in *Salvio*, the court read *Hahn*, as this Court has not, "broadly to bar all non-negligence claims asserted against a manufacturer of prescription drugs[,]" *Salvio*, 810 F. Supp.2d at 755, as did *Rowland*, *see* 34 F. Supp.3d at 569. Absent further argument, the issue of the viability of Plaintiff's express warranty claim is left for another day. The same result applies with respect to Defendants' move for dismissal of Plaintiff's fraud claim, which is premised on cases in which the court had read *Hahn* to require dismissal of all non-negligence claims. *See Kline*, 2008 WL 4787577, at *2-*3; *Colacicco*, 432 F. Supp.2d at 548; *Leonard*, 2010 WL 4961647, at *5.

B. Preemption

Defendants argue that Plaintiff's negligence claims (Counts I–IV) are all preempted, at least in part, under federal law, because they purportedly boil down to allegations that Injectafer should have been labeled and designed differently despite FDA approval of the existing label and design.[13]

[13] Defendants' motion to dismiss argues that "the design defect and failure-to-warn claims are preempted." Counts I through IV contain a host of other theories against Defendants beyond labeling and design, such as negligence by "failing to perform reasonable pre-and post-market testing of the product[,]" "promoting, marketing, and selling Injectafer to physicians for the purposes of off-label use[,]" and "failing to establish and maintain an adequate post-marketing surveillance program[,]" among others. Because these theories have not been briefed and argued, the Court does not address them here.

i. Failure-to-Warn Claims

Defendants first argue that Plaintiff's claims that Defendants should have submitted a different label for FDA approval—warning of additional risks such as the possibility of Severe HPP arising in some patients—should be preempted.[14] Defendants next argue that Plaintiff's pre-approval defective design claims should be preempted to the extent that they contend that Defendants should have altered Injectafer's design, despite FDA approval of the existing design.[15] In sum, Defendants' preemption challenge is limited to Plaintiff's pre-approval failure-to-warn claim and defective design claim.[16]

The Supremacy Clause provides that federal law "shall be the supreme Law of the Land." U.S. Const., Art. VI, cl. 2. State law that conflicts with federal law is therefore "without effect." *Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472, 475 (2013). There are three categories of preemption: (1) express preemption, (2) field preemption, and (3) conflict or impossibility preemption, *see Orson, Inc. v. Miramax Film Corp.*, 189 F.3d 377, 381 (3d Cir. 1999), but only the last one is at issue here.

The defense of impossibility preemption is premised on a contention that a federal regulation would have prohibited the additional warnings that the plaintiff alleges state law requires. The crux of the matter is, thus, whether it is "impossible for [a private party] to comply with both federal and state requirements." *Wyeth v. Levine*, 555 U.S. 555, 571 (2009); *see also*

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[14] Defendants construe the Complaint, in part, as being based on allegations that Defendants provided misleading or incomplete information to the FDA pre-approval, known as a "fraud on the FDA" theory. Plaintiff has, however, confirmed in her briefing and at oral argument that she is not advancing a "fraud on the FDA" theory.

[15] Plaintiff conceded at oral argument that she is not making a post-approval design defect claim. Additionally, Plaintiff's Complaint does not appear to be advancing a theory that Injectafer is so dangerous that it should never be taken by any patient.

[16] Defendants are not seeking dismissal of Plaintiff's claim that Defendants negligently failed to change the Injectafer label post-approval.

Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 1672 (2019) (internal quotations omitted).

The impossibility preemption is a "demanding defense[,]" and there is a presumption against it. *See Wyeth*, 555 U.S. at 565 n.3, 573; *see also id.* at 575 (finding "powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness"). Its application is "for a judge to decide, not a jury." *Merck*, 139 S. Ct. at 1672; *see also id.* at 1678 (noting that "the complexity" of the legal discussion "helps to illustrate why" impossibility preemption should be determined by a judge). Indeed, when impossibility preemption presents a purely legal issue, the Court may decide it on a Rule 12 motion. *See, e.g.*, *PLIVA*, 564 U.S. at 623-24; *Riegel v. Medtronic*, 552 U.S. 312 (2008); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). However, dismissal under Rule 12(b)(6) is appropriate only when "preemption is manifest in the complaint itself." *In re Asbestos Prod. Liab. Litig.*, 833 F.3d 125, 133 n.6 (3d Cir. 2016). In other words, a complaint may be dismissed at the Rule 12 stage if "the plaintiff's own allegations show that a defense exists that legally defeats the claim for relief." Charles Alan Wright, Arthur Miller, Mary Kay Kane & Richard Marcus, *Federal Practice & Procedure* § 1357 (3d ed. 2004). Dismissal on impossibility preemption grounds is particularly tricky on a motion to dismiss. Here, for example, the only "evidence" before the Court is the Complaint and a document on which it is based—Injectafer's Prescribing Information.

In deciding whether impossibility preemption requires the dismissal of a claim, the judge must evaluate the evidence presented and "simply ask . . . whether the relevant federal and state laws 'irreconcilably conflict.'" *Merck*, 139 S. Ct. at 1679 (quoting *Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982)). To put the Court in a position to conduct this evaluation, Defendants

must identify the state law at issue (*e.g.* the requirement that drug manufacturers warn about particular risks of a drug) and the federal law with which it conflicts irreconcilably. To "show[] that federal law prohibited [a] drug manufacturer from adding a warning that would satisfy state law," the drug manufacturer must demonstrate that (1) "the drug manufacturer fully informed the FDA of the justifications for the warning required by state law" by "submitt[ing] all material information to the FDA[,]" and (2) the FDA "informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning." *Id.* at 1678. Such demonstration must be made with "clear evidence," *i.e.*, "evidence that shows the court that the drug manufacturer fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning." *Id.* at 1672.

In making a preemption argument, it is not sufficient for the proponent to contend that if it had submitted a new label—with additional warnings—to the FDA, the FDA *would have* rejected the warning. *See PLIVA*, 564 U.S. at 624 n.8 (noting that the "possibility of impossibility" is not enough for preemption). In other words, the conflict must be real—"[t]he existence of a hypothetical or potential conflict is insufficient to warrant the pre-emption of the state statute." *See Merck*, 139 S. Ct. at 1679 (quoting *Rice*, 458 U.S. at 659). Preemption is further limited in state law failure-to-warn situations where the FDA has *actually* rejected a proposed labeling change through action "taken pursuant to the FDA's congressionally delegated authority." *Id.* For example, the FDA must have "communicate[d] its disapproval of a warning by means of notice-and-comment rulemaking" or by "formally rejecting" a proposed label change in a complete response letter. *Id.*

In support of their impossibility preemption argument, Defendants describe the FDA drug

approval process ("onerous" and "lengthy"). But, standing alone, this recitation does not help them. Regardless of the difficulties associated with the administrative process of the FDA, a drug manufacturer "bears responsibility for the content of its label at all times." *Wyeth*, 555 U.S. at 570-71. Thus, the manufacturer "is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Id.* at 571. Should it become "apparent" that a drug poses a certain risk to the health and safety of persons taking it, the manufacturer of the drug "ha[s] a duty to provide a warning that adequately describe[s] that risk." *Merck*, 139 S. Ct. at 1677 (citing *Wyeth*, 555 U.S. at 570-71).

Defendants refer to the two non-approvable letters from the FDA which cited concerns about "clinically important hypophosphatemia" and recite generally that state law may not countermand the FDA's approval. Specifically, they rely on a single paragraph in the Complaint—stating that the FDA initially sent Defendants non-approvable letters for Injectafer citing a concern about "clinically important hypophosphatemia"—and the FDA's subsequent approval of the drug with its current label, as evidence of the fact that the FDA considered the Severe HPP risk and chose not to warn of it. Defendants do not argue or point to any "evidence" that they proposed a stronger warning to the FDA or that the FDA would have rejected a different warning label. Accordingly, Defendants have not shown that they "fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve changing the drug's label to include that warning." *Merck*, 139 S. Ct. at 1678.[17]

Indeed, in a recent opinion, the Third Circuit reversed a grant of summary judgment on

[17] The lack of allegations or evidence here stands in contrast to other preemption cases. In the brand-name pharmaceutical cases discussed here, and additional ones Defendants rely on such as *Yates v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, 808 F.3d 281 (6th Cir. 2015), courts were able to examine an evidentiary record because they were in the summary judgment or post-trial context.

preemption, finding that the FDA's response letter to a proposed change was asking the defendant to provide additional context, meaning the FDA was not "fully informed" and had not rejected the proposal. *See In re Avandia Marketing, Sales and Prods. Liability Litig.*, 2019 WL 6873681, at *6 (3d Cir. Dec. 17, 2019). The *Avandia* defendant submitted a Prior Approval Supplement to the FDA, seeking to add information to Avandia's label in the wake of several clinical trials to make the warning about cardiac risks "more prominent and clear." *Id.* at *2. The FDA responded with a letter finding the proposed change was "not approvable" because the information presented was "inadequate" and asked the defendant to provide additional information "to address the deficiency." *Id.* The defendant argued that this response letter constituted the FDA's rejection of the proposed change, but the Third Circuit held that the FDA was not "fully informed" under *Wyeth* and *Merck* and had not rejected the proposal but instead sought clarifying information. *Id.* at *6-*7. The defendant, like Defendants here, had not shown that the FDA made a fully informed decision to reject a change to a drug's label and, accordingly, did not meet the high bar to establish and impossibility defense. *Id.* at *6.

Having failed to meet their burden, Defendants attempt to shift it to Plaintiff by suggesting that because "Plaintiff pled no facts supporting a reasonable inference that the FDA lacked knowledge of the existing scientific data when it approved Injectafer," her claims must be dismissed on impossibility preemption grounds. But preemption is an affirmative defense, and it is thus Defendants' burden, not Plaintiff's, to demonstrate that it applies. *See Wyeth*, 555 U.S. at 573.

For the reasons set forth above, the Court finds that Defendants have not met that burden, and thus a ruling on preemption with respect to Plaintiff's failure-to-warn claims would be premature.

ii. Defective Design Claims

Defendants next argue that Plaintiff's pre-approval design defect claims (contained, in part, in Counts I and III) are preempted to the extent they allege that Injectafer should have been designed differently. Among other allegations, Count III of the Complaint asserts Defendants were negligent by "[f]ailing to design Injectafer as to properly minimize the effects on the hormone FGF23 that was known when increased to in turn decrease serum phosphorus[,]" "[f]ailing to counteract in the design the known effects of [FCM,]" and "[d]esigning a product with excessive amounts of iron where the benefits of additional iron were greatly outweighed by the risks of excessive iron injected into the body."

As with the failure-to-warn preemption argument, the Court is unable to address the preemption argument here for two reasons. First, in order to evaluate whether a manufacturer can comply with both state and federal law, courts must determine a manufacturer's legal obligations under each. *See Bartlett*, 570 U.S. at 473-76 (specifically identifying duties under New Hampshire law and how satisfying those duties would require violating federal law). In arguing there is a conflict here, Defendants have not described their duties under any state law or established how those duties conflict with their federal law obligations.

Second, the cases Defendants cite for their preemption argument are inapposite. Defendants rely heavily on *Bartlett*, a generic drug case, but the Supreme Court has long recognized that preemption jurisprudence treats generic and brand-name drugs differently. *See PLIVA*, 570 U.S. at 613-14. Binding precedent does not require preempting the pre-approval defective design claims here, and at this stage, absent adequate argument and evidence, the Court will not extend *Bartlett* beyond its application to generic drugs.

C. Learned Intermediary Doctrine

Defendants argue that Plaintiff's claims for common law fraud (Count V) and violations of the UTPCPL (Count X) must be dismissed pursuant to Pennsylvania's learned intermediary doctrine.

Under the learned intermediary doctrine, when a drug or device is "available only upon prescription of a duly licensed physician, the warning required is not to the general public or to the patient, but to the prescribing doctor." *Coyle v. Richardson-Merrell, Inc.*, 584 A.2d 1383, 1385 (Pa. 1991). A patient in Pennsylvania thus relies on the prescribing physician rather than the prescription drug manufacturer. Defendants assert that the learned intermediary doctrine breaks the chain of justifiable reliance from which it follows that the fraud and consumer protection claims fail as a matter of law.

Both common law fraud and an action brought pursuant to the UTPCPL do require a showing of justifiable reliance by the party defrauded by the misrepresentation. It is an element of common law fraud. *See Colaizzi v. Beck*, 895 A.2d 36, 39 (Pa. Super. 2006). And, it is found in the statutory language of the UTPCPL which prohibits "unfair methods of competition" and "unfair or deceptive acts or practices in the conduct of any trade or commerce[,]" 73 Pa. C.S.A. § 201-03, creating a private cause of action for those who are harmed "as a result of" the defendant's actions. *Id.* at § 201-9.2(a). This causation requirement thus requires a UTPCPL plaintiff to prove "justifiable reliance" on the fraudulent or deceptive conduct, *Hunt v. U.S. Tobacco Co.*, 538 F.3d 217, 223 (3d Cir. 2008) (citing *inter alia Schwartz v. Rockey*, 932 A.2d 885, 897 n.16 (Pa. 2007)), "not simply a causal connection between the misrepresentation and the harm[,]" *id.* at 222.

Plaintiff's fraud claim must be viewed in the context of Section 310 of the Restatement

(Second) of Torts, which states:

> An actor who makes a misrepresentation is subject to liability to another for physical harm which results from an act done by . . . a third person in reliance upon the truth of the representation, if the actor (a) intends his statement to induce or should realize that it is likely to induce action by . . . a third person, which involves an unreasonable risk of harm to the other, and (b) knows (i) that the statement is false. . . .

Section 310 of the Restatement (Second) of Torts. Under Section 310, a plaintiff may prove justifiable reliance by showing that her treating physician relied on the Defendants' alleged misrepresentations. *See Hricik v. Stryker Biotech, LLC*, 89 F. Supp.3d 694, 703-04 (E.D. Pa. 2015) (holding that learned intermediary doctrine did not prevent plaintiff from establishing justifiable reliance element of his fraud claim based on manufacturer's alleged misrepresentations to plaintiff's surgeon); *Taylor v. Danek Med., Inc.*, 1998 WL 962062, at *5 (E.D. Pa. Dec. 29, 1998) (same).

Here, Plaintiff has alleged that Defendants made misrepresentations regarding the safety of Injectafer to Plaintiff's doctor, who acted in reliance on those misrepresentations in prescribing the medication to Plaintiff. Thus the learned intermediary doctrine, as filtered through Section 310, does not demand that Plaintiff's fraud claim be dismissed.[18]

The analysis does not hold in the UTPCPL context because it is a statutory cause of action not subject to the Restatement. The UTPCPL provides consumers a private right of action when they are harmed by goods purchased for personal use. 73 Pa. C.S.A. § 201-9.2(a). But because of the learned intermediary doctrine, Defendants here were obligated to warn doctors, not the patients (consumers). *See Kee,* 871 F. Supp.2d at 411 ("Under Pennsylvania law, a

[18] Defendants rely on a medical device case, *Kee v. Zimmer, Inc.*, 871 F. Supp.2d 405 (E.D. Pa. 2012), to support the contrary. However, in *Kee*, the fraud claim was dismissed because the plaintiffs failed to plead with sufficient particularity—not because the learned intermediary doctrine barred the claim. *Id.* at 411-13.

consumer does not have a cause of action under the UTPCPL against the manufacturer of prescription drugs because prescription drug manufacturers do not have a duty to disclose information directly to consumers.").

A plaintiff cannot satisfy the UTPCPL's "justifiable reliance" requirement when the defendant does not sell the drug directly to the patient and does not have a duty to warn the patient. "Under the learned intermediary doctrine, the drug manufacturer owes a duty of disclosure to the prescribing physician, but it is then the duty of the prescribing physician to communicate any risks or other information about the drug to the patient. In other words, a patient in Pennsylvania cannot justifiably rely on the prescription drug manufacturer; instead, it is the prescribing physician who provides the grounds for justifiable reliance."[19] *Zafarana v. Pfizer, Inc.*, 724 F. Supp.2d 545, 558 (E.D. Pa. 2010); *see also McLaughlin v. Bayer Corp.*, 172 F. Supp.3d 804, 831 (E.D. Pa. 2016). Because the learned intermediary doctrine precludes Plaintiff from pleading a claim under the UTPCPL, Count X is dismissed with prejudice.[20]

D. Negligence

Having addressed the threshold issues, the Court turns to the remaining individual claims and the adequacy of pleadings. In her negligence claims, Plaintiff makes various allegations as to how Defendants negligently designed, developed, manufactured, marketed, promoted, monitored, labeled, sold, and distributed Injectafer. Defendants responds that the alleged facts

[19] Plaintiff's citations to the contrary are inapposite. In *In re Actiq Sales & Marketing Practices Litigation*, 790 F. Supp.2d 313 (E.D. Pa. 2011), the court explicitly distinguished that its ruling was for third-party payors, not plaintiffs bringing tort claims. *See id.* at 318 (rejecting the learned intermediary argument and finding "that cases cited in support of this contention relate to patients bringing personal injury claims rather than third party payors bringing suit for economic recovery under the UTPCPL"). *In re Avandia Marketing, Sales Practices & Product Liability Litigation*, 804 F.3d 633 (3d Cir. 2015), did not address the learned intermediary doctrine. Plaintiff has failed to cite any cases that allowed a UTPCPL claim to proceed against a pharmaceutical manufacturer.

[20] Given that Plaintiff may not maintain a cause of action under the UTPCPL, the Court need not address whether Rule 9(b) governs UTPCPL claims.

are insufficient to state a claim.

"To prevail in a negligence action, a plaintiff 'must show that the defendant had a duty to conform to a certain standard of conduct, that the defendant breached that duty, that such breach caused the injury in question, and actual loss or damage.'" *Berrier v. Simplicity Mfg., Inc.*, 563 F.3d 38, 61 (3d Cir. 2009) (quoting *Phillips v. Cricket Lighters*, 841 A.2d 1000, 1008 (Pa. 2003)). Because the Court has already addressed Count I, it now focuses on Counts II (negligent failure-to-warn), III (negligent design defect), and IV (negligent misrepresentation).

i. Negligent Failure-to-Warn (Count II)

The Pennsylvania Supreme Court has recognized a "continuum . . . within the scope of the general framework of the applicable duty of care" ranging from a warning of dangers to a "stronger warning if justified by the known risks." *Lance*, 85 A.3d at 459-60. These requirements are only imposed where manufacturers or suppliers have actual knowledge—or should, with the exercise of reasonable care, have had actual knowledge—of the existence of unreasonable, nonobvious risks from their products. *See id.*; *see also* Restatement (Second) of Torts § 388 (imposing duty to warn as to dangers that are known or should reasonably be known).

Here, Plaintiff has pled that Defendants failed to warn that Injectafer could cause Severe HPP, despite knowing that Injectafer contained FCM and knowing FCM's potential to cause Severe HPP. Plaintiff pled that during FCM's presence on the European and United States markets, dozens of case reports and important pieces of medical literature linked FCM to Severe HPP. The Complaint includes quotations from several such studies. Additionally, Plaintiff pled that Defendants had knowledge of the link between Injectafer and Severe HPP from their own clinical studies, and that a 2007 non-approvable letter from the FDA listed "clinically important

hypophosphatemia" as a clinical safety concern. Plaintiff pled that, despite Defendants' knowledge of this risk, at all times since introducing Injectafer into the United States market, the drug's label has omitted any reference to Severe HPP or "clinically important hypophosphatemia," has made no reference to the clinical conditions associated with Severe HPP, and has significantly downplayed the risk of regular HPP. These pleadings are sufficient to state a claim for negligent failure-to-warn. Defendants' motion to dismiss Count II for failure to state a claim shall be denied.

ii. Negligent Design Defect (Count III)

Because Plaintiff is not arguing under a negligent design defect post-approval theory, *see supra* n.15, the Court now addresses only the pre-approval portion of Count III.

The parties diverge in their interpretation of *Lance*, in which the Pennsylvania Supreme Court held that negligent design defect claims were cognizable in the prescription drug context. *See* 85 A.3d at 453. Plaintiff is therefore correct that Pennsylvania law does allow for a negligent design claim here. However, Defendants argue that if such a claim is cognizable, it is so only in the following narrow set of circumstances: "[P]harmaceutical companies violate their duty of care [in] introduc[ing] a drug into the marketplace, or continu[ing] a previous tender, with actual or constructive knowledge that the drug is too harmful to be used by anyone." *Id.* at 461.

Lance was a case of first impression, addressing an extreme scenario in which a patient died after taking a prescription diet drug, which was ultimately recalled. The *Lance* holding discussing a drug "too harmful to be used by anyone[,]" *id.*, was addressing this extreme fact pattern. As previously discussed, *see supra* Section III.A, and as *Lance* itself noted, "it is axiomatic that the holding of a judicial decision is to be read against its facts." *See Lance*, 85

A.3d at 453. If *Lance* is limited to its facts, it does not necessarily follow that *Lance*'s pronouncement requiring a drug to be "too harmful" for any use was meant to apply to all kinds of cases, including ones with less extreme fact patterns. At least one other court in this Circuit has recognized that *Lance* is not meant to preclude all other negligent design claims. *See Kramme v. Zimmer, Inc.*, 2015 WL 4509021, at *6 (M.D. Pa. July 24, 2015) ("We do not believe that the Pennsylvania Supreme Court intended to limit negligence claims to only those products too dangerous to be taken by anyone."). Moreover, Pennsylvania has adopted the view of the Restatement (Second) of Torts Section 398, which states: "A manufacturer of a chattel made under a plan or design which makes it dangerous for the uses for which it is manufactured is subject to liability to others whom he should expect to use the chattel or to be endangered by its probable use . . . ." *See also Lance*, 85 A.3d at 445 n.13. The Restatement thus does not require that the design be unsafe for any use, and the Court declines to apply such a burdensome standard here.[21]

Plaintiff's negligence claim concerning a pre-approval design defect contains allegations that: (1) Injectafer is one of several intravenous iron medications on the market, but the only one available in the United States that contains the unique FCM compound; (2) Defendants knew through scientific literature and their own clinical trials of FCM's risks and its potential to cause Severe HPP, but they nevertheless failed to design Injectafer to properly minimize or counteract FCM's known effects; and (3) Defendants designed Injectafer with excessive amounts of iron where the benefits of additional iron were greatly outweighed by the risks of injecting excessive iron into patients. Plaintiff alleges that Defendants breached their duty not to design a product

[21] At oral argument, Defendants conceded that they are not arguing for a requirement to plead a feasible alternative design. *See also Lance*, 85 A.3d at 458 n.36.

"so unreasonably dangerous that its potential harms far outweigh any potential benefits." These factual allegations, taken as true, plausibly allege a defective design negligence claim. Defendants' motion to dismiss Count III as it pertains to pre-approval defective design shall be denied.

iii. Negligent Misrepresentation (Count IV)

Defendants argue in a footnote that Count IV (negligent misrepresentation) should be reviewed under the heightened pleading standard of Rule 9(b). "An argument made only in a footnote is not worthy of credence (other than to be rejected by footnote)." *Schmalz v. Sovereign Bancorp, Inc.*, 868 F. Supp.2d 438, 457 n.14 (E.D. Pa. 2012). Furthermore, Defendants have cited no binding authority requiring this Court to apply the heightened pleading standard of Rule 9(b) to negligent representation claims. *See John Wyeth & Bro. Ltd. v. CIGNA Int'l Corp.*, 119 F.3d 1070, 1076 n.6 (3d Cir. 1997) ("[A]rguments raised in passing . . . but not squarely argued, are considered waived."). Absent such authority, this claim is reviewed under a Rule 8 standard. But, Defendants have advanced no adequate argument as to how negligent misrepresentation was insufficiently pled under that standard. Thus, their motion to dismiss this count for failure to state a claim shall be denied.

E. Fraud (Count V)

Plaintiff alleges that Defendants falsely and fraudulently represented Injectafer to Plaintiff, the public, and the medical community to induce more Injectafer prescriptions while concealing the drug's known risks.

Under Pennsylvania law, "to establish common law fraud, a plaintiff must prove: (1) misrepresentation of a material fact; (2) scienter; (3) intention by the declarant to induce action; (4) justifiable reliance by the party defrauded upon the misrepresentation; and (5) damage to the

party defrauded as a proximate result." *Colaizzi*, 895 A.2d at 39.

Averments of fraud must be pled with particularity. Fed. R. Civ. P. 9(b). The purpose of the heightened pleading requirement is to disclose material facts sufficient to notify the adverse party of the claims against which it will have to defend itself. *Martin v. Lancaster Battery Co.*, 606 A.2d 444, 448 (Pa. 1992). Whether a claim has been pled with the required specificity is determined by viewing the allegations in the context of the complaint as a whole. *See Yacoub v. Lehigh Valley Med. Assocs., P.C.*, 805 A.2d 579, 589 (Pa. Super. 2002) (en banc).

As pled, the fraud claim falls short of what Rule 9 requires. Most of the facts and allegations are recycled from the negligence claims with words like "falsely," "fraudulently," and "willfully" tacked on to allege the legal prerequisites of fraud. Plaintiff pleads that, "[i]n reliance upon these false representations, Plaintiff and her physicians were induced to, and did use, Injectafer"—but Rule 9 demands more than these conclusory statements to satisfy the heightened pleading requirement. *See, e.g.*, *Kee*, 871 F. Supp.2d at 413 ("Plaintiff fails to allege facts supporting the nature of her reliance or specific representations Defendant made relating to the reliance."). Plaintiff cites several out-of-Circuit cases in arguing that the pleading standard should be relaxed given that the issues here are complex and she has not "truly begun the discovery process." But Rule 9 says what it says. The "who, what, when, where and how" of Defendants' alleged fraud—the "first paragraph of any newspaper story"—is missing here. *See In re Rockefeller*, 311 F.3d at 217. Count V shall therefore be dismissed without prejudice.

F. Breach of Express Warranty (Count VIII)

Plaintiff pleads that Defendants breached Injectafer's express warranty, alleging Defendants represented through language in their labeling, advertising, and marketing materials that Injectafer was safe for patient use. Defendants respond that Plaintiff's breach of express

warranty claim is barred because Plaintiff did not plead pre-suit notice.

Under Pennsylvania law, "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise." 13 Pa. C.S.A. § 2313(a).[22] Plaintiff must "within a reasonable time after he [or she] discovers or should have discovered any breach notify the seller of breach or be barred from any remedy." 13 Pa. C.S.A. § 2607(c)(1).

Plaintiff contends that the Complaint pleads that Defendants had actual or constructive notice of the issues with Injectafer, which should suffice to achieve the same goal as pre-suit notice. However, the case that Plaintiff herself cites rejected this argument. *See Am. Fed'n of State County & Mun. Emps. ("AFSCME") v. Ortho-McNeil-Janssen Pharms., Inc.*, 2010 WL 891150, at *6 (E.D. Pa. Mar. 11, 2010). In rejecting the plaintiff's argument on actual or constructive notice satisfying Section 2607(c)(1), the *AFSCME* court explained that the plaintiff had confused the term "notice" with the Section 2607(c)(1) obligation to "notify" the seller. *Id.* "[T]he purpose of notification under Section 2607(c) is to allow the seller an opportunity to resolve the dispute regarding an alleged breach before the buyer initiates a lawsuit. Therefore, even assuming that Defendants were aware that the [prescription drugs] were defective, Defendants . . . were denied the opportunity to negotiate or settle this claim without judicial involvement." *Id.* The court held that Section 2607(c) requires plaintiffs to plead that they provided "reasonable notification . . . in some manner" to state a viable claim for recovery. *Id.* at

[22] Defendants argue that Injectafer's labeling is federally mandated and therefore the statements within the labels do not constitute express warranties designed to induce the purchase of the medication. Both cases Defendants cite are inapposite, as they are about chemical disinfectant products labeled under the Federal Insecticide, Fungicide, and Rodenticide Act—not prescription drugs. *See Sowers v. Johnson & Johnson Med.*, 867 F. Supp. 306 (E.D. Pa. 1994); *Kenepp v. Am. Edwards Lab.*, 859 F. Supp. 809 (E.D. Pa. 1994).

*7. Plaintiff here failed to allege that she provided Defendants with pre-suit notification, and Count VIII is therefore dismissed without prejudice.

G. Punitive Damages

Finally, Defendants argue that punitive damages are an "extreme remedy" available in the most exceptional matters, and this is not one of them. *See Phillips v. Cricket Lighters*, 883 A.2d 439, 445 (Pa. 2005). In response, Plaintiff points to specific pleadings in the Complaint that she argues warrant the application of punitive damages.

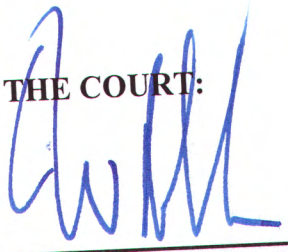
"Punitive damages may be awarded for conduct that is outrageous, because of the defendant's evil motive or his reckless indifference to the rights of others." *Hutchison v. Luddy*, 870 A.2d 766, 770 (Pa. 2005); *see also* Restatement (Second) of Torts § 908(1) ("Punitive damages are damages, other than compensatory or nominal damages, awarded against a person to punish him for his outrageous conduct and to deter him and others like him from similar conduct in the future."). In Pennsylvania, a punitive damages claim must be supported by evidence sufficient to establish that: (1) a defendant had a subjective appreciation of the risk of harm to which the plaintiff was exposed; and, (2) he acted, or failed to act, in conscious disregard of that risk. *Hutchison*, 870 A.2d at 772.

Taking Plaintiff's Complaint as true, she has alleged that Defendants had actual knowledge from scientific literature and clinical studies that Injectafer causes Severe HPP; that they were aware of the differences between mild or asymptomatic HPP and Severe HPP; and that they suppressed this information from patients and the medical community in Injectafer's labeling and marketing. Read together under a motion to dismiss standard, these pleadings are sufficient to state a claim for punitive damages.

An appropriate order follows.

January 28, 2020

BY THE COURT:



WENDY BEETLESTONE, J.